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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,533	12/06/2001	Thomas W. Konowalchuk	LFT000 CIP2	3288

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EXAMINER	
HUI, SAN MING R	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 02/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/021,533	Applicant(s) KONOWALCHUK ET AL.	
	Examiner San-ming Hui	Art Unit 1617	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-34 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This is a continuation-in-part of US application Serial No. 09/795,279.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of copending Application No. 10/016189. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between two copending application is that 10/016189 teaches the method of inactivating a virus while the instant claims teaches a method of treating an inflammation or lesion caused by a virus. It would have been obvious to one skill in the art when the invention was made to employ the method of 10/016189 in a method of treating an inflammation or lesion caused by the same virus.

One of ordinary skill in the art would have motivated to employ the method of 10/016189 in a method of treating an inflammation or lesion caused by the same virus because both methods of the copending application 10/016189 employing the same composition of the instant application and therefore similar antiviral therapeutic effect would have been reasonably expected.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pamukoff (Canadian Patent: CA 1221640 from the Information Disclosure Statement received December 6, 2001), Poli et al. (Food Chemistry 1979; 4:250-258 from the Information Disclosure Statement received December 6, 2001), Bhatia et al. (Indian Journal of Animal Sciences 1998; 68(6): 518-520 from the Information Disclosure Statement received December 6, 2001), and Simmons et al. (US Patent 5,405,602).

Pamukoff teaches that 1-10% ethyl alcohol containing composition for treating viral infections broadly, in particularly the infections that are caused by Herpes virus such as Herpes Simplex 1, Herpes Simplex 2, and common cold viruses (See

particularly page 2, first paragraph; also page 7-9, Examples 2-5; also claims 1 and 2). Pamukoff also teaches that this antiviral composition can be formulated into creams (See particularly page 2, line 3).

Poli et al. teaches that glycolic acid is virucidal against herpevirus, orthomyxovirus, and Rhabdovirus (See particularly page 253, Table 1). Poli also teaches that the acid is in 0.1M concentration (See page 252, second paragraph). 0.1M of glycolic acid (Molecular Weight = 76g) is equal to 0.76 % wt.

Bhatia et al. teaches that hydrochloric acid is effective in inactivation of goat-pox virus which is in the Poxviridae family (See particularly page 519, col. 1, Table 1 and col. 2, third paragraph).

Simmons teaches that 1,4-butanediol is useful in an antiviral method against HIV infection (See particularly claim 1).

The references do not expressly teach the employment of 1-10% ethyl alcohol or 1,4-butanediol and glycolic acid or hydrochloric acid into the same method of treating an inflammation or lesion caused by viruses. The references do not expressly teach the pH of the composition to be 2.45. The references do not expressly teach the weight ratio of glycolic acid to be 0.6%. The references do not expressly teach the method of treating an inflammation or lesion caused by molluscum contagiosum.

It would have been obvious to one skill in the art when the invention was made to employ 0.6% of glycolic acid or hydrochloric acid and 1-10% ethyl alcohol or 1,4-butanediol and adjusted the final pH to 2.45 in a method of treating an inflammation or lesion caused by viruses including molluscum contagiosum.

One of ordinary skill in the art would have motivated to employ 0.6% of glycolic acid or hydrochloric acid and 1-10% ethyl alcohol or 1,4-butanediol and adjusted the final pH to 2.45 in a method of treating an inflammation or lesion caused by viruses including molluscum contagiosum because the agents herein are known to be useful to inactivating viruses individually. Therefore, employing these known antiviral agents herein in a method of treating inflammation or lesion caused by the viruses would have been reasonably expected to have a similar antiviral therapeutic effect since inactivating viruses would prevent further infection by the virus and thereby treating the lesions caused by the viruses. Furthermore, the optimization of result effect parameters (pH, amount of the active) is obvious as being within the skill of the artisan, absent evidence to the contrary. In addition, hydrochloric acid is known to be useful in inactivating goat-pox virus. Therefore, employing hydrochloric acid containing composition in a method to treat an inflammation or lesion caused by other poxviruses including molluscum contagiosum would have been reasonably expected to be similarly effective.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
February 7, 2002

MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600